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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/365,065	07/30/99	COLLINS	10847/002001

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EXAMINER

ZEMAN, R

ART UNIT	PAPER NUMBER
1645	10

DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/365,065

Applicant(s)

Collins

Examiner

Robert A. Zeman

Group Art Unit

1645



☒ Responsive to communication(s) filed on Jul 27, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-21 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-21 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5 and 7

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1645

DETAILED ACTION

Response to Amendment

Claims 1-21 are pending and currently under consideration.

Objections to the Specification Maintained

Theo objection to the specification for the use of the trademarks Texas Red™, Oregon Green™, Cascade™, Nonidet P40 and Triton-X 100 is maintained for reasons of record. It is noted that Applicant has failed to address this objection in his response to the Office Action mailed on 3-20-2000.

Claim Rejections Withdrawn

35 USC § 102

The rejection of claims 20 and 21 under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chandler et al. (U.S. Patent 5,981,180) is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1645

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The rejection of claims 1-21 under 35 U.S.C. 103(a) as being unpatentable over Kortright et al.(U.S. Patent 4,870,003) in view of Jackson et al. (U.S. Patent 5,776,709) is maintained essentially for reasons of record.

Applicant argues that claim 1 relates to a method for simultaneously measuring both members of a binding pair in a biological sample and that said method includes: providing a solid phase reagent comprising a particle coated with capture antibodies having specific affinities for member A of the binding pair; contacting a biological sample with said solid phase reagent to form the first reacted particle; contacting the first reacted particle first antibodies having specific binding affinities for member A and labeled with a given label, and with second antibodies having specific binding affinities for member B and labeled with a second label forming the second reacted particle, and measuring the labels on the second reacted particle using flow cytometry. Applicant further argues that while Kortright et al. discloses a system for detecting HIV antigen and anti-HIV antibody they do not teach or suggest that two antibodies, one having specificity for member A and one having specificity for member B, that are differently labeled that can be used to simultaneously measure both members of a binding pair. Applicant further argues that Kortright et al. only discloses a qualitative measurement while the instant claims are drawn to both qualitative and quantitative measurements. Additionally, Applicant argues that

Art Unit: 1645

while Jackson et al. disclose flow cytometry methods for analyzing populations of leukocytes using two or more fluorescent labels they do not teach or suggest a method or a kit for the simultaneous measurement of both members of a binding pair. Applicant concludes that Jackson et al. does not remedy the deficiencies of the disclosure of Kortright et al. since it does not teach or suggest that both members of a binding pair can be measured simultaneously. Applicants arguments have been fully considered and have been deemed not persuasive.

First it is noted that applicant is arguing limitations not found in the claims which do not require that the "first" and "second" labels are different. Secondly, Kortright et al. disclose a solid-phase immunoassay for the simultaneous detection of both members of a binding pair in physiological fluid through the utilization of labeled antibodies with specific binding affinities said binding pair members. Kortright et al. further disclose methods consisting of coating a solid phase reagent with a capture antibody (anti-HIV monoclonal antibody); exposing said solid phase reagent to a biological sample to bind one member of the binding pair; and adding labeled antibodies to detect the levels of each member of the binding pair (see column 4, lines 1-32). Kortright et al, however, disclose the use of enzyme labels for measuring binding pair levels and the level of the second binding pair member is determined indirectly as an increase over the "spiked" positive control. Jackson et al. disclose not only the use of fluorescently labeled antibodies but also the methods for using multiple stains simultaneously in flow cytometry (see example 1 in columns 12 and 13 for an example) which allows for the direct measurement of the level of each binding pair member. Jackson et al also disclose the benefit of using multiple

Art Unit: 1645

fluorescent labels as opposed to other labeling techniques (such as enzyme labels). Multiple fluorescent labels “provide(s) a means for obtaining a maximum amount of information with the minimal sample manipulation, resulting in time savings both in sample preparation and instrument data acquisition” The method allows detection of two or more subpopulations depending on the number of fluorochrome-labels used. Therefore, it would have been obvious to one of skill in the art to use the fluorochrome labeling disclosed by Jackson et al. in the methods disclosed by Kortright et al. in order to reap the benefits of direct measurement (both qualitative and quantitative) of each label (and hence each binding pair member) as well as the reduction in sample preparation and data acquisition. One would have a reasonable expectation of success since Kortright et al. suggest the use of other labeling systems, specifically “fluorescers” (see column 7 lines 29-32). Additionally, the methods disclosed by Kortright et al. can be applied to a myriad of binding pairs including: various viruses and antibodies; enzymes and its ligands or substrates; cytokines and their receptors; and vitamins and their receptors to name a few. Applicant is reminded that the aforementioned rejection is based on the **combination** of the cited references.

Conclusion

No claim is allowed.

Art Unit: 1645

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 308-7991. The examiner can be reached between the hours of 7:30 am and 4:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, Donna Wortman, Primary Examiner can be reached at (703) 308-1032 or the examiner's supervisor, Lynette Smith, can be reached at (703)308-3909.

Robert A. Zeman

October 6, 2000


DONNA WORTMAN
PRIMARY EXAMINER